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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,066	04/18/2006	Hirokazu Matsumoto	0233120123	2077

22428 7590 09/12/2007
FOLEY AND LARDNER LLP
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EXAMINER	
DUTT, ADITI	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,066	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Appendix A*.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, 17-22, drawn to a monoclonal antibody reacting specifically with a polypeptide of SEQ ID NO: 1, a pharmaceutical composition, and a diagnostic agent comprising the antibody, and a method of producing the antibody.

Group II, claim(s) 10, 12-14, drawn to a method of quantifying a polypeptide of SEQ ID NO: 1 using the monoclonal antibody.

Group III, claim(s) 11, drawn to a method of diagnosing a disease associated with a polypeptide of SEQ ID NO: 1 using the monoclonal antibody.

Group IV, claim(s) 15-16, drawn to a hybridoma producing the monoclonal antibody.

Group V, claim(s) 23, drawn to a method of preventing and/or treating diseases, by administering the monoclonal antibody to a mammal.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
Group I recites the special technical feature of a monoclonal antibody reacting specifically to SEQ ID NO: 1, which is not required by the other products of Group IV. Claim 1 is anticipated by prior art. Ehlert et al (International Publication No. WO200236625-A2, dated 10 May 2002), teach polypeptides related to human prokineticin 1 and 2, represented by an amino acid sequence that is 100% identical to SEQ ID NO: 1 of the instant invention, and antibodies specific to the polypeptide (see pages 28-30; Appendix A). Therefore, claim 1 lacks a special technical feature and cannot share one with the other claims.

Group II recites the special technical feature of quantifying a polypeptide using the monoclonal antibody, which is not required by the other methods of Groups III and V.

Group III recites the special technical feature of diagnosing a disease linked to the polypeptide using the monoclonal antibody, which is not required by the other methods of Groups II and V.

Group IV recites the special technical feature of a hybridoma, which is not required by the other products of Group I.

Group V recites the special technical feature of preventing or treating diseases by administering the antibody to a mammal, which is not required by the other methods of Groups II, and III.

3. A further restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The applicant is required to elect *one* sequence for prosecution, from one of the following groups:

A) SEQ ID NO: 1

B) SEQ ID NO: 2

C) SEQ ID NO: 3

4. The inventions listed as Groups A-C do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In the instant case, the different inventions of Groups (A-C) are unique protein molecules of different

lengths and are composed of different amino acids. Accordingly, each of the different protein sequences are not so linked under PCT Rule 13.1 and are thus placed in thirteen different inventive groups numbered A-C. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. Furthermore, each of the sequences represents a different protein with unique and diverse functional features.

Note: This is a Restriction requirement, not an Election of species. In order to be fully responsive, Applicant must select one from Inventions I-V and one from groups A-C.

5. Species Election

A) Disease

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) Central nervous system disorder

b) Motor dysfunction

c) Endocrine disease

The claims are deemed to correspond to the species listed above in the following manner: Claim 23

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above diseases have distinct pathology and the treatment would involve varying levels of success. For example, the special technical feature of Central nervous system disorder is not shared by the other diseases.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. In response to this Office Action/Election requirement, applicant must elect one from Groups I-V and A-C (amino acid sequence), and must additionally elect a species of diseases.

7. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if

one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(l).

Notice of Rejoinder

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

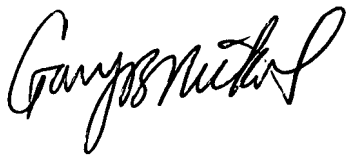
Advisory Information

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037. The examiner can normally be reached on M-F.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD
01 September 2007



GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

APPENDIX A

<!--StartFragment-->RESULT 3
AAE24385
ID AAE24385 standard; protein; 81 AA.
XX
AC AAE24385;
XX
DT 04-OCT-2002 (first entry)
XX
DE Human prokineticin 2 mature protein.
XX
KW Human; prokineticin 2; gastrointestinal motility; intestinal cancer;
KW irritable bowel syndrome; gastrointestinal reflux disease; diarrhoea;
KW diabetic gastroparesis; chronic constipation; malabsorptive disorder;
KW inflammatory bowel disorder; analgesic; infectious disease.
XX
OS Homo sapiens.
XX
PN WO200236625-A2.
XX
PD 10-MAY-2002.
XX
PF 01-NOV-2001; 2001WO-US047969.
XX
PR 03-NOV-2000; 2000US-0245882P.
XX
PA (REGC) UNIV CALIFORNIA.
XX
PI Zhou Q, Ehlert FJ;
XX
DR WPI; 2002-479752/51.
DR N-PSDB; AAD39322.
XX
PT New isolated human prokineticin 1 and 2 polypeptides that stimulate
PT gastrointestinal smooth muscle contraction, useful for improving impaired
PT gastrointestinal motility in irritable bowel syndrome, chronic
PT constipation.
XX
PS Claim 3; Page 81; 86pp; English.
XX
CC The invention relates to human prokineticin 1 and 2 polypeptides that
CC stimulate gastrointestinal smooth muscle contraction and nucleic acid
CC molecules encoding such polypeptides. Polypeptides of the invention are
CC useful for treating disorders involving impaired gastrointestinal
CC motility. They are useful for stimulating gastrointestinal motility in
CC disorders such as irritable bowel syndrome, diabetic gastroparesis, post-
CC operational ileus, chronic constipation and gastrointestinal reflux
CC disease. The prokineticin antagonists are useful for inhibiting
CC gastrointestinal motility in conditions of diarrhoea, malabsorptive
CC disorders, inflammatory bowel disorders, infectious diseases and
CC intestinal cancers. The antagonists also act as analgesics. The present
CC sequence is human prokineticin 2 mature protein
XX
SQ Sequence 81 AA;

  Query Match   100.0%; Score 461; DB 5; Length 81;
  Best Local Similarity   100.0%; Pred. No. 4.2e-41;
  Matches   81; Conservative   0; Mismatches   0; Indels   0; Gaps   0;

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Qy          1 AVITGACDKDSQCGGGMCCAVSIWVKSIRICTPMGKLGDSCHPLTRKVPFFGRRMHHTCP 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 AVITGACDKDSQCGGGMCCAVSIWVKSIRICTPMGKLGDSCHPLTRKVPFFGRRMHHTCP 60

Qy         61 CLPGLACLRTSFNRFICLAQK 81
              |||||||||||||||||||||
Db         61 CLPGLACLRTSFNRFICLAQK 81
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